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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0655]

Animal Generic Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "Animal Generic Drug User Fee Act." The purpose of the meeting is to discuss the proposed recommendations for the reauthorization of the Animal Generic Drug User Fee Act (AGDUFA IV) for fiscal years 2024 through 2028.

DATES: The public meeting will be held virtually on October 26, 2022, from 2 p.m. to 4 p.m. eastern time. Either electronic or written comments on this meeting must be submitted by November 9, 2022. See the SUPPLEMENTARY INFORMATION section for registration dates and further information.

ADDRESSES: The public meeting will be hosted via a live virtual webcast.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. eastern time at the end of Wednesday, November 9, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-N-0655 for "Animal Generic Drug User Fee Act; Public Meeting; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6888, lisa.kable@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a virtual public meeting to discuss proposed recommendations for the reauthorization of AGDUFA, which authorizes FDA to collect user fees and use them for the

process of reviewing new animal generic drug applications and associated submissions. The authority for AGDUFA expires September 30, 2023. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal generic drug review process for future fiscal years. Section 742(d)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)(21 U.S.C. 379j-13(d)(4)) requires that, after holding negotiations with regulated industry and periodic consultations with stakeholders, and before transmitting the Agency's final recommendation to Congress for the reauthorized program (AGDUFA IV), we do the following: (1) present the recommendation to the relevant congressional committees, (2) publish such recommendations in the *Federal Register*, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) consider such public views and comments and revise such recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the congressional committees.

FDA considers the timely review of abbreviated new animal drug applications (ANADAs) to be central to the Agency's mission to protect and promote human and animal health. Prior to 2009, the timeliness and predictability of the generic new animal drug review program was a concern. The Animal Generic Drug User Fee Act enacted in 2008 (Pub. L. 110-316; hereinafter referred to as "AGDUFA I") amended the FD&C Act to authorize FDA's first-ever generic animal drug user fee program. AGDUFA I provided FDA with additional funds to enhance the performance and predictability of the generic new animal drug review process. Furthermore, the authorization of AGDUFA I enabled FDA's continued assurance that generic new animal drug products are safe and effective.

Under AGDUFA I, FDA agreed to meet review performance goals for certain submissions over 5 years from FY 2009 through FY 2013. The purpose of establishing these

review performance goals was to ensure the timely review of ANADAs and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions and have enabled FDA to reduce the time for the application review process for generic new animal drugs without compromising the quality of the Agency's review.

With the reauthorization of AGDUFA for an additional 5 years under AGDUFA II (FY 2014 to FY 2018), FDA agreed to further enhance and improve the review process. The AGDUFA II authorization enhancements included developing Question Based Review Process for Bioequivalence Submissions and shortening review time for key submission types. Additionally, there were Chemistry, Manufacturing, and Controls (CMC) enhancements, including permitting manufacturing supplements to be resubmitted as "Supplement-Changes Being Effected in 30 Days" if deficiencies are not substantial for manufacturing supplements requiring prior approval according to § 514.8(b) (21 CFR 514.8(b)); permitting comparability protocols as described in § 514.8(b)(2)(v) to be submitted as protocols without substantial data in a JINAD file; and developing guidance for a two-phased CMC technical section submission and review process under the JINAD file. Finally, the proportion of revenue collected from user fees was redistributed as follows: application fees from 30 percent to 25 percent; product fees from 35 percent to 37.5 percent; and sponsor fees from 35 percent to 37.5 percent.

Most recently, AGDUFA was reauthorized for an additional 5 years under AGDUFA III (FY 2019 to FY 2023). The AGDUFA III authorization enhancements included reducing performance goal review times for nearly all submission types, requiring 100 percent electronic submission and requiring an "approved by FDA" statement along with an ANADA number on approved animal drugs by September 30, 2023. Additionally, the inflation adjuster was changed from a fixed rate to a variable rate and the final year offset provision was eliminated. Finally, a new provision was added that any excess collections would be used to offset workload adjuster fee increases, if invoked.

FDA has published a number of reports that provide useful background on AGDUFA I, AGDUFA II, and AGDUFA III. AGDUFA-related *Federal Register* notices, guidances, legislation, performance reports, and financial reports can be found at: https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa.

II. Topics for Discussion at the Public Meeting

In preparing the proposed recommendation to Congress for AGDUFA reauthorization, we conducted discussions with the regulated industry, and consulted with stakeholders as required by the law. We began the AGDUFA reauthorization process with a public meeting held on May 20, 2021 (86 FR 18986, April 12, 2021). Following the May 2021 public meeting, FDA conducted negotiations with regulated industry and continued regular consultations with public stakeholders from July through October 2021. As directed by Congress, FDA posted minutes of these discussions on its website at https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings.

The proposed enhancements in AGDUFA IV will address priorities identified by stakeholders, regulated industry, and FDA. The full description of these proposed recommendations can be found in the proposed AGDUFA IV Performance Goals and Procedures Letter. FDA intends to post the full text of the proposed AGDUFA IV Performance Goals and Procedures Letter at https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings, no later than one week prior to the public meeting. FDA will post the agenda approximately 5 days before the meeting at https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online at https://fda.zoomgov.com/meeting/register/vJItcuCtqD4pGPe2DNgbbQZYaRswsTm9iRM no later than October 24, 2022. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Also, please self-identify as a

member of one of the following stakeholder categories: scientific or academic experts, veterinary professionals, patients and consumer advocacy groups, or the regulated industry, and whether you are requesting a scheduled presentation. Early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

If you need special accommodations due to a disability, please contact Lisa Kable (see FOR FURTHER INORMATION CONTACT) no later than October 20, 2022.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate. We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by October 24, 2022. All requests to make oral presentations must be received by October 20, 2022, 11:59 p.m. eastern time. If selected for presentation, any presentation materials must be emailed to Lisa Kable (see FOR FURTHER INFORMATION CONTACT) no later than October 24, 2022. No commercial or promotional material will be permitted to be presented at the public meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at https://www.regulations.gov. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings.

Dated: September 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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